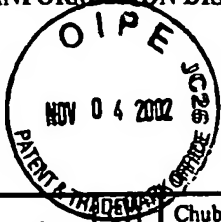
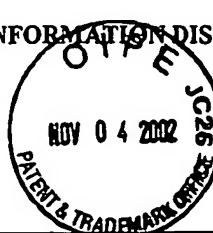


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| FORM PTO - 1449 | | ATTORNEY DOCKET NO.: STK-081 | TECH CENTER 1600/2800 NOV 05 2002 |
| INFORMATION DISCLOSURE STATEMENT | | APPLICANTS: Chubinskaya et al. | |
|  | | SERIAL NO.: 10/081,163 | |
| | | FILING DATE: February 20, 2002 | |
| | | GROUP: 1645 | |
| 6 | | Chubinskaya et al. "Human Articular Chondrocytes Express Osteogenic Protein-1", <u>J. Histochem. Cytochem.</u> 48(2):239-250 (2000). | |
| 6 | C12 | Chubinskaya et al. "Osteogenic Protein-1 is a Repair Factor that is Endogenously Expressed in Human Articular Cartilage", 4 th International OP-1 Conference, Whistler, BC, Canada (March 23-25, 2001). | |
| 6 | C13 | Chubinskaya et al. "Osteogenic Protein-1 is a Chondroprotective Factor Endogenously Expressed by Human Articular Chondrocytes", 3rd Symposium - Cartilage and Cartilage Repair in the New Millennium, Gothenburg, Sweden, (April 27-29, 2000). | |
| 6 | C14 | Dudley, A.T. et al. "A Requirement for Bone Morphogenetic Protein-7 during Development of the Mammalian Kidney and Eye", <u>Genes Dev.</u> 9(22):2795-2807 (1995). | |
| 6 | C15 | Dudley, A.T. et al. "Overlapping Expression Domains of Bone Morphogenetic Protein Family Members Potentially Account for Limited Tissue Defects in BMP-7 Deficient Embryos" <u>Dev. Dyn.</u> 208(3):349-362 (1997). | |
| 6 | C16 | Duneas, N. et al. "Transforming Growth Factor-beta 1: Induction of Bone Morphogenetic Protein Genes Expression during Endochondral Bone Formation in the Baboon, and Synergistic Interaction with osteogenic protein-1", <u>Growth Fact.</u> 15(4):259-277 (1998). | |
| 6 | C17 | Ekblom, P. "Genetics of Kidney Development", <u>Curr. Opin. Neph. Hyperten.</u> 5(3):282-287 (1996). | |
| 6 | C18 | Francis-West, P. et al. "Signaling Interactions during Facial Development", <u>Mech. Dev.</u> 75:3-28 (1998). | |
| 6 | C19 | Frank, B.S. "OP-1 in synovial fluid", 2001 Annual Scientific Meeting of the American College of Rheumatology, San Francisco, CA. (November 10-15, 2001). | |
| 6 | C20 | Godin, R.E. et al. "Regulation of BMP7 Expression during Kidney Development", <u>Development</u> 125(17):3473-3482 (1998). | |
| 6 | C21 | Haaijman A. et al. "Correlation between ALK-6(BMPR-1B) Distribution and Responsiveness to Osteogenic Protein-1 (BMP)-7 in Embryonic Mouse Bone Rudiments", <u>Growth Fact.</u> 17:177-192 (2000). | |
| 6 | C22 | Heikinheimo, K. et al. "Activin and Bone Morphogenetic Protein (BMP) Signaling during Tooth Development", <u>Eur. J. Oral Sci.</u> 106(1):167-173 (1998). | |
| 6 | C23 | Helder, M.N. et al. "Bone Morphogenetic Protein-7 (Osteogenic Protein-1, OP-1) and Tooth Development", <u>J. Dent. Res.</u> 77(4):545-554 (1998). | |
| 6 | C24 | Helder, M.N. et al. "Expression Pattern of Osteogenic Protein-1 (Bone Morphogenetic Protein-7) in Human and Mouse Development", <u>J. Histochem. Cytochem.</u> 43(10):1035-1044 (1995). | |
| 6 | C25 | Helder, M. et al. "Coordinate Expression of Osteogenic Protein-1 (Bone Morphogenetic Protein-7) and Bone Morphogenetic Protein-3 (Osteogenin) during Mouse and Human-Development", <u>J. Bone and Mineral Res.</u> 8(1):S316 (1993). | |
| 6 | C26 | Hofmann, C. et al. "Analysis of Limb Patterning in BMP-7-Deficient Mice", <u>Dev. Genetics</u> 19(1):43-50 (1996). | |
| EXAMINER | | DATE CONSIDERED 10/28/09 | |

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|---|-----|---|
| FORM PTO - 1449 | | ATTORNEY DOCKET NO.: STK-081 |
| INFORMATION DISCLOSURE STATEMENT | | APPLICANTS: Chubinskaya et al. |
|  | | SERIAL NO.: 10/081,163 |
| | | FILING DATE: February 20, 2002 |
| | | GROUP: 1645 |
| | C27 | Hogan, B.L.M. "Bone Morphogenetic Proteins: Multifunctional Regulators of Vertebrate Development", <u>Genes Dev.</u> 10:1580-1594 (1996). |
| | C28 | Jena, N. et al. "BMP-7 Null Mutation in Mice: Developmental Defects in Skeleton, Kidney, and Eye", <u>Exp. Cell Res.</u> 230(1):28-37 (1997). |
| | C29 | Jeppsson, C. et al. "OP-1 for Cervical Spine Fusion: Bridging Bone in Only 1 of 4 Rheumatoid Patients but Prednisolone did not Inhibit Bone Induction in Rats", <u>Acta. Orthop. Scand.</u> 70(6):559-563 (1999). |
| | C30 | Karsenty, G. et al. "BMP-7 is Required for Nephrogenesis, Eye Development, and Skeletal Patterning", <u>Ann. NY Acad. Sci.</u> 785:98-107 (1996). |
| | C31 | Katagiri, T. et al. "Skeletal Abnormalities in Doubly Heterozygous BMP4 and BMP7 Mice", <u>Dev. Genet.</u> 22(4):340-348 (1998). |
| | C32 | Kim, R.Y. et al. "Bmp6 and Bmp7 are Required for Cushion Formation and Septation in the Developing Mouse Heart", <u>Dev. Bio.</u> 235:449-466 (2001). |
| | C33 | King, J.A. et al. "The Role of BMPs and GDFs in Development of Region-Specific Skeletal Structures", <u>Ann. NY Acad. Sci.</u> 785:70-79 (1996). |
| | C34 | Kingsley, D.M. "What Do BMPs Do in Mammals - Clues From the Mouse Short-Ear Mutation", <u>Trends in Genet.</u> 10(1):16-21 (1994). |
| | C35 | Lechner, M.S. et al. "The Molecular Basis of Embryonic Kidney Development", <u>Mech. Dev.</u> 62(2):105-120 (1997). |
| | C36 | Lyons, K.M. et al. "Colocalization of BMP-7 and BMP-2 RNAs Suggests that these Factors Cooperatively Mediate Tissue Interactions During Murine Development" <u>Mech. Dev.</u> 50(1):71-83 (1995). |
| | C37 | Lyons, K.M. et al. "The DVR Gene Family in Embryonic Development", <u>Trends Genet.</u> 7(11-12):408-412 (1991). |
| | C38 | Macias, D. et al. "Role of BMP-2 and OP-1 (BMP-7) in Programmed Cell Death and Skeletogenesis During Chick Limb Development" <u>Development</u> 124(6):1109-1117 (1997). |
| | C39 | Merrihew et al. "Osteogenic Protein-1 and its Receptors Could be a Chondroprotective Factor in Human Articular Cartilage", 3rd International Conference on Bone Morphogenetic Proteins, p. 92, Lake Tahoe, (June 7-11, 2000). |
| | C40 | Merrihew et al. "Age-Related Changes in Endogenous Osteogenic Protein-1 in Human Knee Articular Cartilage", Orthopedic Research Society Meeting, San Francisco, USA, (February 2001). |
| | C41 | Mintzer, K.A. et al. "lost-a-fin Encodes a Type 1 BMP Receptor, Alk8, Acting Maternally and Zygotically in Dorsal-ventral Pattern Formation", <u>Development</u> 128:859-869 (2001). |
| | C42 | Muehleman et al., "Immunohistochemical Localization of Osteogenic Protein-1 and its Receptor in Rabbit Articular Cartilage", Trans ORS 46(2):1050, Orlando, USA, (March 12-15, 2000). |
| | C43 | Nakashima, M. et al. "Transforming Growth Factor-beta Superfamily Members Expressed in Rat Incisor Pulp", <u>Arch. Oral Biol.</u> 43(9):745-751 (1998). |
| | C44 | Nishimatsu, S. et al. "Genes for Bone Morphogenetic Proteins are Differentially Transcribed in Early Amphibian Embryos", <u>Biochem. Biophys. Res. Comm.</u> 186(3):1487-1495 (1992). |
| EXAMINER <i>Harry Counts</i> | | DATE CONSIDERED <i>10/28/04</i> |

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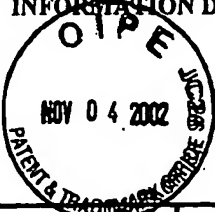
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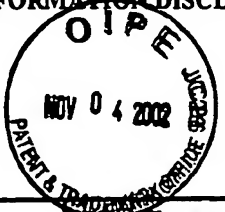
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| FORM PTO - 1449 | | ATTORNEY DOCKET NO.: STK-081 |
| INFORMATION DISCLOSURE STATEMENT | | APPLICANTS: Chubinskaya et al. |
|  | | SERIAL NO.: 10/081,163 |
| | | FILING DATE: February 20, 2002 |
| | | GROUP: 1645 |
| ✓ | C45 | Özkaynak, E. et al. "Murine Osteogenic Protein (OP-1): High Levels of mRNA in Kidney", <u>Biochem. Biophys. Res. Comm.</u> 179(1):116-123 (1991). |
| ✓ | C46 | Özkaynak, E. et al. "Osteogenic Protein-1 mRNA in the Uterine Endometrium", <u>Biochem. Biophys. Res. Comm.</u> 234(1):242-246 (1997). |
| ✓ | C47 | Özkaynak, E. et al. "Osteogenic Protein-2: a New Member of the Transforming Growth Factor-beta Superfamily Expressed Early in Embryogenesis", <u>J. Biol. Chem.</u> 267(35):25220-25227 (1992). |
| ✓ | C48 | Özkaynak, E., et al. "Organ Specific Expression of Selected TGF- β Superfamily Members", Keystone Symposium on Growth and Differentiation Factors In Vertebrate Development, Keystone, Co., USA, <u>J. Cell. Biochem.</u> , Suppl 0(16 Part F):81 (April 3-10, 1992). |
| ✓ | C49 | Peterkova, R. et al. "Bone morphogenetic proteins (BMPs) and Tooth Development", <u>Trends in Glycosci. Glycoth.</u> 9(47):253-265 (1997). |
| ✓ | C50 | Rauch, F. et al. "Temporal and Spatial Expression of Bone Morphogenetic Protein-2, -4, and -7 During Distraction Osteogenesis in Rabbits", <u>Bone</u> 26(6):611-617 (2000). |
| ✓ | C51 | Ray, R.P. et al. "Twisted Perspective: New Insights Into Extracellular Modulation of BMP Signaling During Development", <u>Cell</u> 104:801-804 (2001). |
| ✓ | C52 | Ripamonti, U. et al. "Bone Morphogenetic Proteins: from Developmental Biology to Molecular Therapeutics", <u>South African J. Sci.</u> 91(6):277-280 (1995). |
| ✓ | C53 | Roelen, B.A.J. et al. "Differential Expression of BMP Receptors in Early Mouse Development", <u>Int. J. Dev. Biol.</u> 41(4):541-549 (1997). |
| ✓ | C54 | Sampath, T K, "Role of Osteogenic Protein-1 (OP-1) in Growth, Development and Repair of Bone", <u>J. Cell. Biochem.</u> S17e:107 (1993). |
| ✓ | C55 | Sato, M. et al. "Mechanical Tension-Stress Induces Expression of Bone Morphogenetic Protein (BMP)-2 and BMP-4, but Not BMP-6, BMP-7, and GDF-5 mRNA, During Distraction Osteogenesis", <u>J. Bone Min. Res.</u> 14(7):1084-1095 (1999). |
| ✓ | C56 | Solursh, M. et al. "Osteogenic Protein-1 is Required for Mammalian Eye Development", <u>Biochem. Biophys. Res. Comm.</u> 218(2):438-443 (1996). |
| ✓ | C57 | Suzuki, A. et al. "Differential Expression of <i>Xenopus</i> BMPs in Early Embryos and Tissues", <u>Zoolog. Sci. (Japan)</u> 10(1):175-178 (1993). |
| ✓ | C58 | Thesleff, I. et al. "The Enamel Knot: A Putative Signaling Center Regulating Tooth Development", <u>Cold Spring Harb. Symp. Quant. Biol.</u> 62:257-67 (1997). |
| ✓ | C59 | Thomadakis, G. et al. "Immunolocalization of Bone Morphogenetic Protein-2 and -3 and Osteogenic Protein-1 during Murine Tooth Root Morphogenesis and in Other Craniofacial Structures", <u>Eur. J. Oral Sci.</u> 107:368-377 (1999). |
| EXAMINER <i>Ang Const</i> | | DATE CONSIDERED <i>10/28/04</i> |

| | | | |
|---|-----|---|--|
| FORM PTO - 1449 | | ATTORNEY DOCKET NO.: STK-081 | TECH CENTER 1600/2600 NOV 05 2002 RECEIVED |
| INFORMATION DISCLOSURE STATEMENT | | APPLICANTS: Chubinskaya et al. | |
|  | | SERIAL NO.: 10/081,163 | |
| | | FILING DATE: February 20, 2002 | |
| | | GROUP: 1645 | |
| GC | C60 | Thomas, R. et al. "Androgen-Dependent Gene Expression of Bone Morphogenetic Protein 7 in Mouse Prostate", <u>Prostate</u> 37(4):236-245 (1998). | |
| GC | C61 | Toyono, T. et al. "Temporal Changes in Expression of Transforming Growth Factor-beta Superfamily Members and Their Receptors during Bovine Preodontoblast Differentiation in vitro", <u>Arch. Oral Biol.</u> 42(7):481-488 (1997). | |
| GC | C62 | Toyono, T. et al. "Expression of TGF-beta Superfamily Receptors in Dental Pulp", <u>J. Dent. Res.</u> 76(N9):1555-1560 (1997). | |
| GC | C63 | Vainio, S. et al. "Inductive Tissue Interactions, Cell Signaling, and the Control of Kidney Organogenesis", <u>Cell</u> 90:975-978 (1997). | |
| GC | C64 | Valecillos, M. E. F., "Immunolocalization Of Osteogenic Protein (OP-1) In Developing Murine Teeth", Joint Meeting of the International Assoc. For Dental Res., The American Assoc. Of Dental Res. and the Canadian Assoc. of Dental Res., Chicago, IL, USA, <u>J. Dent. Res.</u> 72 (Abstr. Spec. Issue):110 (March 10-14, 1993). | |
| GC | C65 | Vukicevic, S. et al. "Localization of Osteogenic Protein-1 (Bone Morphogenetic Protein-7) During Human Embryonic Development: High Affinity Binding to Basement Membranes", <u>Biochem. Biophys. Res. Commun.</u> 198(2):693-700 (1994). | |
| GC | C66 | Vukicevic, S. et al. "Localization of the Osteogenic Protein-1 During Early Human Embryonic Development", Fourth Workshop On Cells And Cytokines In Bone And Cartilage, Davos, Switzerland, <u>Calcif. Tissue Int.</u> 50(Suppl. 1):A31 (January 11-14, 1992). | |
| Not Considered | C67 | Vukicevic, S., "Synthesis and Function of Osteogenic Protein-1 (BMP-7) and Bone Morphogenetic Protein-3 (Osteogenin)", Bone Research Branch, National Institute of Dental Research, NIH, Bethesda, MD School of Medicine, University of Zagreb, Croatia (publication date unknown). | |
| GC | C68 | Wall, N.A. et al. "Expression of Bone Morphogenetic Protein-4 (BMP-4), Bone Morphogenetic Protein-7 (BMP-7), Fibroblast Growth Factor-8 (FGF-8) and Sonic Hedgehog (SHH) During Branchial Arch Development in the Chick", <u>Mech. Dev.</u> 53(3):383-392 (1995). | |
| GC | C69 | Wawersik, S. et al. "BMP7 Acts in Murine Lens Placode Development", <u>Dev. Bio.</u> 207(1):176-188 (1999). | |
| GC | C70 | Woolf, A.S. et al. "Roles of Growth Factors in Renal Development", <u>Curr. Opin. Neph. Hyperten.</u> 6(1):10-14 (1997). | |
| GC | C71 | Wozney, J. M. "The Bone Morphogenetic Protein Family: Multifunctional Cellular Regulators in the Embryo and Adult", <u>Eur. J. Oral Sci.</u> 106(Suppl 1):160-166 (1998). | |
| GC | C72 | Wozney, J.M. et al. "Growth Factors Influencing Bone Development", <u>J. Cell Sci. Suppl.</u> 13:149-156 (1990). | |
| GC | C73 | Yamamoto, T. "Immunohistochemical Localization of Bone Morphogenetic Proteins and Their Receptors in Rat and Human Articular Cartilage", <u>Med. J. Kagoshima Univ.</u> 50(4):123-131 (1999). | |
| EXAMINER <i>Henry Canuto</i> | | DATE CONSIDERED 10/28/04 | |

* C67 was not considered because could not determine relevance because no date was disclosed. Therefore, could not determine if reference was available as prior art.

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| FORM PTO - 1449 | | ATTORNEY DOCKET NO.: STK-081 |
| INFORMATION DISCLOSURE STATEMENT | | APPLICANTS: Chubinskaya et al. |
| | | SERIAL NO.: 10/081,163 |
| | | FILING DATE: February 20, 2002 |
| | | GROUP: 1645 |
| 6c | C74 | Yazaki, J. "Immunohistochemical Localization of Bone Morphogenetic Proteins and the Receptors in Epiphyseal Growth Plate", <u>Anticancer Res.</u> 18(4A):2339-2344 (1998). |
| 6c | C75 | Yeh, L.C.C. et al. "Osteogenic Protein-1 Regulates Insulin-Like Growth Factor-I (IGF-I), IGF-II, and IGF-Binding Protein-5 (IGFBP-5) Gene Expression in Fetal Rat Calvaria Cells by Different Mechanisms", <u>J. Cell Phys.</u> 175(1): 78-88 (1998). |
| 6c | C76 | You, L. et al. "Bone Morphogenetic Proteins and Growth and Differentiation Factors in the Human Cornea", <u>IOVS</u> 40(2):296-311 (1999). |
| EXAMINER <i>Gary Smith</i> | | DATE CONSIDERED 10/28/04 |

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INFORMATION DISCLOSURE STATEMENT

APPLICANTS: Chubinskaya et al.

SERIAL NO.: 10/081,163

FILING DATE: February 20, 2002 GROUP: 1645

U.S. PATENT DOCUMENTS

| EXAM. INIT. | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUB CLASS | FILING DATE IF APPROPRIATE |
|----------------|----|--------------------|----------|--------------|-------|--------------|-------------------------------|
| GC | A3 | 4,857,456 | 08/15/89 | Urist | 435 | 7 | |
| GC | A4 | 5,834,179 | 11/10/98 | Jones et al. | 435 | 4 | |
| GC | A5 | 6,171,586 B1 | 01/09/01 | Lam et al. | 424 | 130.1 | |

FOREIGN PATENT DOCUMENTS

| EXAM. INIT. | | DOCUMENT NUMBER | DATE | COUNTRY CODE | CLASS | SUB CLASS | FILING DATE | ABSTRACT ONLY | ENGLISH LANG Y/N |
|----------------|------------------|--------------------|----------|-----------------|-------|--------------|----------------|------------------|---------------------|
| GC | B1 ^a | 93/04692 | 03/18/93 | WO | | | | | Y |
| GC | B2 ^a | 99/60164 | 11/25/99 | WO | | | | | Y |
| GC | B3 ^a | 00/04183 | 01/27/00 | WO | | | | | Y |
| GC | B4 ^a | 00/61774 | 10/19/00 | WO | | | | | Y |
| GC | B5 ^a | 00/73509 A2 | 12/07/00 | WO | | | | | Y |
| GC | B6 ^a | 01/07067 A2 | 02/01/01 | WO | | | | | Y |
| GC | B7 ^a | 01/20018 A2 | 03/22/01 | WO | | | | | Y |
| GC | B8 ^a | 01/21836 A2 | 03/29/01 | WO | | | | | Y |
| GC | B9 ^a | 01/53531 A2 | 07/26/01 | WO | | | | | Y |
| GC | B10 ^a | 01/62927 A2 | 08/30/01 | WO | | | | | Y |
| GC | B11 ^a | 01/87323 A2 | 11/22/01 | WO | | | | | Y |
| GC | B12 ^a | 02/06534 A2 | 01/24/02 | WO | | | | | Y |
| GC | B13 ^a | 0 561 297 B1 | 10/14/98 | EP | | | | | Y |
| GC | B14 ^a | 0 601 106 B1 | 05/17/00 | EP | | | | | Y |

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| FORM PTO - 1449 | | | | ATTORNEY DOCKET NO.: STK-081 | | | | | |
| SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT | | | | APPLICANTS: Chubinskaya <i>et al.</i> | | | | | |
| | | | | SERIAL NO.: 10/081,163 | | | | | |
| | | | | FILING DATE: February 20, 2002 GROUP: 1645 | | | | | |
| U.S. PATENT DOCUMENTS | | | | | | | | | |
| EXAM. INIT. | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUB CLASS | FILING DATE IF APPROPRIATE | | |
| Be | A6 | 5,707,810 | 01/13/98 | Smart et al. | 435 | 6 | | | |
| Ge | A7 | 6,194,376 B1 | 02/27/01 | Kuberasampath et al. | 514 | 2 | | | |
| | | | | | | | | | |
| FOREIGN PATENT DOCUMENTS | | | | | | | | | |
| EXAM. INIT. | | DOCUMENT NUMBER | DATE | COUNTRY CODE | CLASS | SUB CLASS | FILING DATE | ABSTRACT ONLY | ENGLISH LANG Y/N |
| Ge | B15 ^u | 96/39431 | 12/12/96 | WO | | | | | Y |
| Ge | B16 ^o | 98/54572 | 12/03/98 | WO | | | | | Y |
| OTHER ART, JOURNAL ARTICLES, ETC. | | | | | | | | | |
| EXAM. INIT. | OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication) | | | | | | | | |
| Ge ^o | C77 | International Search Report for International Patent Application No. PCT/US02/05551, dated February 18, 2003, 10 pages. | | | | | | | |
| Ge ^u | C78 | Bauer et al., (1999), "Biochemical Markers of Bone Turnover and Prediction of Hip Bone Loss in Older Women: The Study of Osteoporotic Fractures", J. Bone Mineral Res., 14:1404-1410. | | | | | | | |
| EXAMINER <i>Nary Gumb</i> | | | | | DATE CONSIDERED 10/28/04 | | | | |

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